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(54) Title: SELF-EXPANDING MEMORY METAL STENT AND METHOD OF MAKING IT

(57) Abstract: A method of making a self-expanding luminal stent from a precursor of shape-memory material, in which the precursor is expanded in a radial direction to a radially to an expanded configuration and then heat-set in the expanded configuration, thereafter being radially compressed to a delivery configuration, the feature characterising the invention being the step imposing on the precursor during heat-setting the precursor in its expanded configuration a force which deforms the precursor in a direction orthogonal to said radial direction. The invention is advantageously applied to a stent precursor made by laser slitting of a memory metal alloy tube. Expanding the tube radially opens the slits up into a pattern of zigzag rings but has the consequence also that the axial length of each such ring is shorter, the more the radius of the tube is expanded. Thus, when such a stent is deployed into the body of a patient, the deployed length of the stent is typically about 9 % shorter than the compressed delivery configuration of the stent. By use of the present invention, such a stent "remembers" to expand lengthwise when it is deployed into the body, the consequence that its deployed length in the body is virtually the same or identical to its length in the compressed delivery configuration.

SELF-EXPANDING MEMORY METAL STENT AND METHOD OF MAKING IT

In one aspect, this invention relates to a method of making a self-expandable luminal stent from a precursor of shape-memory material, in which the precursor is expanded radially to an expanded configuration and then heat-set in the expanded configuration, thereafter being radially compressed to a delivery configuration

In another aspect this invention relates to a self-expanding luminal stent comprising a matrix of struts of shape-memory material, which has been heat-set to a radially-expanded configuration, and which is compressible to a relatively small radius configuration for delivery under radial constraint to a desired site within a human body.

US-A-5,707,386, of the present applicant, discloses a stent and a method of making a stent, such as is the subject of the present specification. The content of US-A-5,707,386 is hereby incorporated by this reference into the present disclosure. The stent is made by laser slitting of a Nitinol memory metal cylinder, expanding the slitted cylinder radially, performing a heat treatment on the expanded cylinder to heat-set the cylinder material in the expanded configuration, at lower temperature radially compressing the cylinder, whereby martensitic twinning phenomena allow the stent at low temperature to be stable in its small diameter configuration. In use of the stent, it can be delivered in the small diameter configuration to a site of surgery within the body. Body heat raises the temperature of the stent and, under this thermo-dynamic stimulus, the material of the stent transforms from Martensite to Austenite, with consequent reversion to the large

diameter configuration, effective for its stenting purpose.

During delivery to the site of surgery, and after installation there, flexibility of the stent is desirable. The US patent discloses ways in which to enhance the flexibility of the memory metal stents.

The stents disclosed in the US patent have in common with many other stents a tendency to reduce somewhat in length (typically as much as 9 % of the length of the stent) upon radial expansion from the delivery to the deployed configuration. In a simple case, in which the stent slit pattern creates a multiplicity of zigzag rings running around the circumference of the stent cylinder, expansion of the stent in the radial direction causes the individual legs of each zigzag ring to rotate away from each other, so that the slits open up into diamond-shaped apertures. It will be appreciated that, the more the inclination of the legs of the zigzag to the longitudinal axis of the stent, the shorter is the overall length along the axis of the stent of each zigzag ring. Thus, with the zigzag rings in essentially end to end abutment, and with each of the zigzag rings individually having a slightly smaller length along the axis of the stent, when in the expanded configuration, the inevitable result is that the overall length of the stent produces in proportion to the amount of radial expansion.

This axial shortening is perceived by some people, and for some applications, as a disadvantage. It can introduce uncertainties into the precision of placing of the stent lengthwise along the bodily lumen. Also, the stent will likely have a tendency to shrink in length,

over a period of say, two weeks, following deployment, which would tend to draw down the length of the stented tissue around the stent, not to the advantage of the patient.

One aim of the present invention is to ameliorate these problems.

According to one aspect of the present invention there is provided, in a method of making a self-expanding luminal stent as identified above, the step of axially expanding the precursor lengthwise along its lumen, and heat-setting the precursor when in said axially expanded configurations.

By heat setting the memory metal precursor while it is being held at a length more or less identical to that which it has in its radially compressed configuration, it should be possible to bring about radial expansion of the stent within the body, without any change in the overall length of the stent during the radial expansion process.

The particular stent construction of above-mentioned US 5,707,386, with its many gaps, instead of bridges, between radially adjacent zigzag hoops, is well-adapted to accept the axial expansion for the heat-setting step.

In another aspect of the present invention, there is provided a self-expanding luminal stent which is characterised in that a length of the stent in the delivery configuration, and a corresponding length in the expanding configuration, are substantially the same.

Some stents are arranged with a helical pattern of cells. It will be appreciated that the present invention is applicable to these helically arranged stents, to stents characterised by a pattern of closed

loops stacked along an axis, and indeed to any other stents of shape memory material.

Although stents are usually more or less cylindrical in overall form, some are frusto-conical and some are formed from cylindrical zones, tapered zones and frusto-conical zones, along the length of the stent. For example, an oesophageal stent may have a mid-length section which is cylindrical, a frusto-conical zone at each end of the stent, with the wide end of the frusto-cone defining each end of the stent length, and a curved tapered transition zone between the cylinder and the frusto-cone, one towards each end of the stent. Further, the flexibility of stents of this concept can be varied along the length of the stent. In the case of the oesophageal stent, the mid-length cylindrical zone is made highly flexible, whereas the tapered and frusto-conical zones at each end of the stent are kept relatively stiff, by not providing any gaps between abutment points of one zigzag ring with the next adjacent ring. In such a case, the axial expansion of the precursor stent, during heat setting of the stent, is all confined to the flexible zone of the stent, where there is some capacity for relative movement of the struts of the stent cell matrix, relative to each other. Such capacity is lacking in the relatively less flexible end zones of the stent matrix.

For imposing the axial expansion on the precursor, during the heat-setting step, it is convenient to place a complementary mandrel within the lumen of the stent precursor, and then to engage each opposite end of the stent precursor with a tool which is essentially annular and fits over the mandrel. With a circumferential engagement of the annular tool, such as a collar or

sleeve, at each end of the stent precursor, all that remains is to move the two annular tools apart from each other, until the ends of the stent precursor are spaced apart, along the length of the mandrel, by more or less the same distance as that which spaces them apart when the stent precursor is in its compressed delivery configuration. The two annular tools are then fixed in their spaced-apart locations, and the stent precursor can then be heat treated, in order that the shape memory metal of the stent should "remember" its axially and radially expanded configuration.

For a better understanding of the present invention, and to show more clearly how the same may be carried into effect, reference will now be made, by way of example, to the accompanying drawings, in which:

Fig. 1 is a side view of a laser-cut cylinder of shape memory metal, transverse to its longitudinal axis;

Fig. 2 is a side view of the Figure 1 cylinder, but with the cylinder having been radially expanded on a cylindrical mandrel;

Fig. 3 is the same view of the cylinder of Figure 1 and 2, showing the cylinder stretched lengthways on the mandrel;

Drawing Figure 1 is taken from US-A-5,707,386 and the description of the stent in that patent should be referred to by the skilled reader, for additional information about the stent background of the present invention. As can be seen, a multiplicity of slits parallel to the long axis A of the stent give rise to diamond-shaped apertures in the cylindrical wall of the stent precursor, upon expansion from the Figure 1 to the Figure 2 disposition. Halfway along the length of each

of these slits is a vertex of the basic diamond cell. Without any further interference with the memory metal cylinder, all of the vertices of all of the diamond-shaped cells would be uninterrupted, leaving the stent precursor cylinder relatively inflexible in bending about the long axis A, whether the stent cylinder is compressed or expanded.

However, if some of the vertices of some of the diamond cells, halfway along the length of each of the axial slits, are cut through, then small gaps 5 are provided, which enhance the flexibility of the stent in bending relative to the longitudinal axis A.

Furthermore, this cutting through of the vertices gives a certain freedom for the opposite ends of the stent, in the expanded configuration of Figure 2, to move away from each other by a relative rotation of the various struts 2 which form the walls of the diamond cells, relative to each other, allowing the gaps 5 to widen. Looking at Figure 1, 2 and 3, with the basic cylinder length X shown in Figure 1, the cylinder in its "natural" radially expanded configuration of Figure 2 has a length X-L, being up to about 91%of the original length X. However, pulling the opposite ends of the Figure 2 stent apart, in order to get back to the original cylinder length X, will have the effect of causing the various struts to rotate relative to each other to accommodate the tensile stress, leading to an arrangement of struts somewhat as shown in Figure 3.

Figures 2 and 3 show one particular arrangement for imposing this axial tension on the stent precursor, by way of example. Thus, a solid cylindrical mandrel 20 has an outside diameter corresponding to the desired inside diameter of the stent in deployment

configuration. The stent precursor is introduced onto this mandrel at a sharp-pointed mandrel end (not shown), so as to expand the precursor gently up from its original Figure 1 diameter to the desired Figure 2 and 3 diameter. Once the precursor is satisfactorily mounted on the cylindrical mandrel 20, each of its ends receives a collar 22, as shown in Figures 4 and 5.

The collars 22 create a stent which features tapered end portions having a taper angle which corresponds to the cone angle ramp surface 24 on each of the collars 22. It will be appreciated that the bore within each collar 22 is dimensioned to fit snugly on the outside diameter of the mandrel 20.

The ramp surfaces 24 of each collar 22 are provided with isosceles triangular raised areas 28 having an outline complementary in shape to the axial end portion of one of diamond cells at the end of the stent precursor, in order that the tensile stress on the precursor can be applied to the end ring of diamonds by the raised areas 28.

Figs. 2,3 show a set screw 30 in a threaded bore of the collar 22, for clamping the collar in any desired position on the cylindrical surface of the mandrel 20. The two collars 22, one at each end of the stent precursor, are set on the mandrel at a distance apart as desired, normally to bring the length of the stent cylinder back to its original length X.

Once the collars 22 are clamped to the mandrel bar 20, the entire assembly is then transferred to an oven for heat treating, in accordance with procedures well-known to those skilled in the art of designing and

building Nitinol shape memory alloy stents, in order that the stent cylinder should "remember" its configuration as set in Fig. 3, expanded radially and lengthwise back to length X.

In a variant, these construction techniques can be employed to make a covered stent graft which also has an expanded length more or less identical to that in its compressed configuration. In one especially convenient arrangement, the mandrel 20 accepts a covering of graft material, then the stent precursor, and then further graft material is wrapped around the stent precursor. The subsequent heat treatment not only sets the desired length of the stent precursor but also, at the same time, fuses the graft material radially inside the stent precursor to that outside the stent, through the apertures of the stent matrix. Then, when the stent is compressed to its slim delivery disposition, there is little or no circumferential creasing of the graft material to accommodate any length change of the memory metal stent as it is compressed down from its large diameter to its small diameter configuration. This itself is a significant advantage of the contribution to the art which this invention brings.

In an especially preferred embodiment, the stent graft material is expanded polytetrafluoroethylene (ePTFE), and the ePTFE on the luminal surface of the stent is present only as two spaced bands one at each end of the flexible mid-length zone of the stent. In contrast, the abluminal surface of the stent carries the ePTFE coating for the entire length between the ends of the spaced ePTFE bands, and the width of the bands themselves. In this way, the graft material on the abluminal surface, between the two luminal bands, is not

attached to the metal stent and is free to move relative to the metal stent. What this delivers, therefore, is a stent graft having remarkable flexibility, remarkable compactness in the delivery disposition, with the minimum of creases in the graft covering, and minimal length change upon expansion at the site of surgery. Additionally, with the tapered end zones not covered, they can serve better to inhibit unwanted migration of the stent lengthwise along the bodily lumen, after the stent has been placed at a desired site in that lumen. To make all these technical effects available in one simple device is a major advance in the art and of major value to medical practitioners seeking better stent grafts.

In a variant (not shown), a torsion can be applied to the stent precursor, when setting it up for heat treatment, whereby there is a relative rotation between the two ends of the stent, as the stent is deployed from its delivery disposition to its deployed disposition. To the extent that this displaces from face to face relationship the cut faces 5 of a stent such as in Figs. 1 and 2, this torsion and relative rotation can endow the stent with enhanced flexibility in bending when in the deployed configuration. Thus, in a preferred embodiment, one collar 22 is pulled away from the other and at the same time twisted on the mandrel relative to the other by, say, around 15° to 20°, and then held fast to the mandrel for the heat-setting of the stent.

There may be situations in which it is advantageous to hold the stent twisted during heat-setting but NOT impose any length extension on the stent. For exampke,

the surgeon might wish to have a stent which gets shorter as it expands radially, in order to relieve lengthwise tension on stent-supported luminal tissue radially outside the stent cylinder. Such a method represents another aspect of the present invention.

Those skilled in the art will bring to their appreciation of this specification the general background knowledge of the person of ordinary skill in this art. Thus, for example, the skilled reader will already have a good understanding of production process steps which are a normal part of stent graft production. These process steps include, by way of example, the parameters for selection of stent materials, the parameters which govern the heat-setting of stent workpieces of shape memory materials, specifically Nitinol, and the processing steps of laser cutter programming and cut sequencing, workpiece polishing and workpiece sterilisation. The above description is of preferred embodiments within the scope of the appended claims, and variations within the scope of the claims will be appreciated by skilled readers.

C L A I M S

1. A method of making a self-expanding luminal stent from a precursor of shape-memory material, in which the precursor is expanded in a radial direction to a radially to an expanded configuration and then heat-set in the expanded configuration, thereafter being radially compressed to a delivery configuration, characterised by the step of:

imposing on the precursor during heat-setting the precursor in said expanded configuration a force which deforms the precursor in a direction orthogonal to said radial direction.

2. A method according to claim 1, wherein the force is aligned in the axial direction.

3 A method according to claim 1 wherein the axial expansion is achieved by imposing axial tensile stress on the precursor after radial expansion.

4. A method according to any one of the preceding claims, wherein the force is aligned with the circumferential direction of the precursor whereby to urge one end of the precursor to rotate about its axis relative to the opposite end of the precursor.

5. Method according to any one of the preceding claims including the step of gripping portions at opposite ends of the stent, each inside a gripping ring, at least one of which is moveable axially on a former, on which the stent is mounted.

6. Method according to any one of the preceding claims, including the step of applying to the axially-expanded precursor a stent covering material, the step of heat-setting the precursor also serving to fix the covering to the precursor.

7. A self-expanding luminal stent comprising a matrix of struts of shape-memory material, which has been heat-set to a radially-expanded configuration, and which is compressible to a relatively small radius configuration for delivery under radial constraint to a desired site within a human body, characterised in that a length of the stent in the delivery configuration, and a corresponding length in the expanded configuration, are substantially the same.

8. Stent as claimed in claim 7 wherein the matrix of struts defines a number of complete turns around the circumference around the lumen, each turn being linked to an adjacent turn by link elements which connect a link point of one ring with an adjacent link point of the adjacent turn.

9. Stent as claimed in claim 8 wherein the turns are turns of a helix.

10. Stent as claimed in claim 8 wherein the turns are closed rings.

11. Stent as claimed in claim 8, 9 or 10 wherein the turns comprise struts which are arranged zigzag fashion and which , during expansion, rotate relative to each other

12. Stent as claimed in any one of claims 8 to 11, wherein the axial length of one turn, between link points on opposite ends of said turn, remains unchanged, or substantially unchanged, during said expansion.

13. Stent as claimed in any one of claims 8 to 12 wherein the link elements are axially-extensible by a change of configuration.

Fig. 1

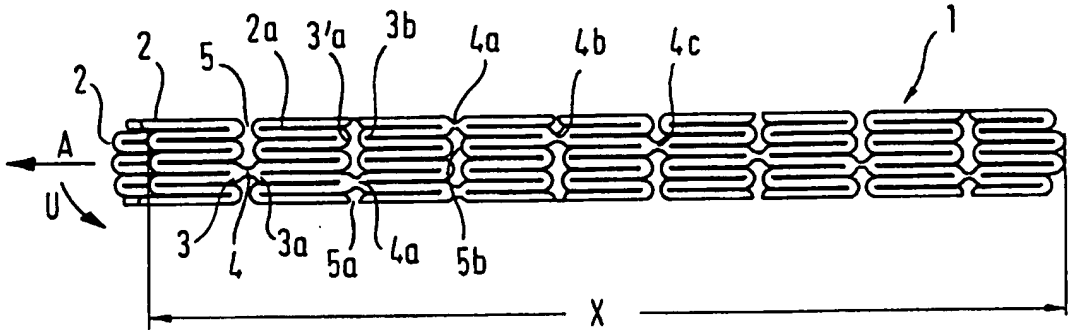

Fig. 2

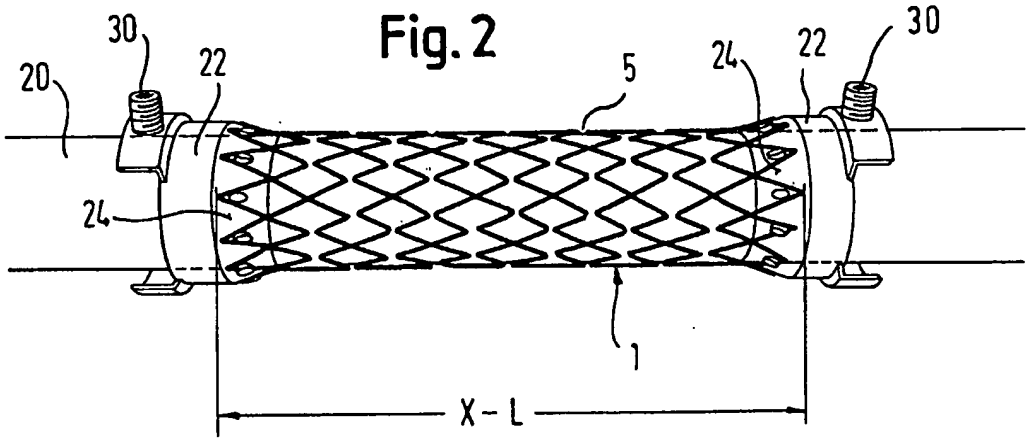

Fig. 3